§ 81.327 Montana.

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
Montana–TSP				
City of Missoula	X			
Colstrip area		X		
City of Columbia Falls	X			
Missoula area		X		
Butte area	[1]X			
Billings area		X		
Great Falls area		X		
East Helena area		X		
Remainder of State				X

[1] EPA designation replaces State designation.

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[FR Doc. 85–9424 Filed 4–25–85; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Part 723

[OPTS–50032B; 2742–1]

Premanufacture Notification Exemption; Exemption for Chemical Substances Manufactured in Quantities of 1,000 Kg or Less Per Year

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Section 5(a)(1)(A) of the Toxic Substances Control Act (TSCA) requires that persons notify EPA before they manufacture or import a new chemical substance for commercial purposes. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer or importer of any new chemical substance from the provisions of section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk of injury to health or the environment. EPA is granting a limited exemption under section 5(h)(4) from the requirements of section 5(a)(1)(A) for persons who manufacture certain new chemical substances in quantities of 1,000 kilograms or less per year. To ensure that these chemical substances will not present an unreasonable risk, EPA has included procedural safeguards, including a 21-day review, and other conditions in the exemption.

DATE: This rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on May 10, 1985. This rule is effective June 10, 1985.

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SUPPLEMENTARY INFORMATION: OMB control number 2070–0012.

I. Background

A. Introduction

Under section 5(a)(1)(A) of TSCA, any person who intends to manufacture or import a new chemical substance for commercial purposes must notify EPA 90 days before manufacture or import begins. A new chemical substance is any chemical substance that is not on the Chemical Substance Inventory compiled by EPA under section 8(b) of TSCA.

The requirement to submit premanufacture notices (PMNs) for new chemical substances became effective on July 1, 1979, 30 days after publication of the Initial Inventory. EPA issued final Premanufacture Notice Requirements and Review Procedure, published in the **Federal Register** of May 13, 1983 (48 FR 21722). In the **Federal Register** of September 13, 1983 (48 FR 41132), the Agency clarified certain provisions of the rule, made a non-substantive amendment to the timing of the submission of the notice of commencement of manufacture, and stayed other provisions of the rule. The rule became effective October 26, 1983. Since the beginning of the program in 1979, EPA has reviewed more than 4,000 PMNs.

Section 5(h)(4) of TSCA allows the Administrator, upon application and by rule, to exempt a new chemical substance or category of new chemical substances from any requirement of section 5 if he or she determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to health or the environment. The Agency issued an exemption for certain chemical substances used in or for instant photographic film articles published in the **Federal Register** of June 4, 1982 (47 FR 24308), and an exemption for new polymeric substances which was published in the **Federal Register** of November 21, 1984 (49 FR 46066). With this notice, the Agency is issuing an exemption for certain low volume chemical substances.

This exemption was developed in response to petitions from the Chemical Manufacturers Association (CMA) and other industry trade groups. Notice of receipt of the CMA and other petitions was published in the **Federal Register** of November 3, 1981 (46 FR 54688); proposed rules were published in the **Federal Register** of August 4, 1982 (47 FR 33896, 47 FR 33924). These rules, which would have exempted certain site-limited intermediates and low volume substances, were proposed as § 723.10 of Subpart A. The final rule is promulgated as § 723.50 of Subpart B, but includes only substances manufactured or imported at 1,000 kilograms or less per year.

The 60-day comment period on the proposals ended on October 4, 1982. EPA received 52 comments on the site-limited intermediate and low volume proposal from trade associations, chemical manufacturers, an environmental organization, and other interested persons. At the request of the Natural Resources Defense Council and other groups, a public hearing was held on November 1, 1982, in Washington, D.C. Seven organizations or individuals made oral comments on the proposal at the hearing. EPA reopened the public comments period at the hearing, extending it for 30 days, to give participants at the hearing an opportunity to answer questions from EPA on their comments. Seven organizations provided comments during the extended period.

EPA has summarized its response to the major public comments received during the rulemaking. This summary, together with copies of the public comments and a transcript of the hearing, is included in the public record.

B. Exemption Requests

The CMA petition, received on May 21, 1981, requested exemptions for:

1. Site-limited intermediates.

2. Chemical substances produced in quantities of 25,000 pounds or less per year.

3. Polymers whose precursor monomers are on the TSCA Inventory.

In addition, CMA requested an exemption that would authorize EPA to allow manufacture of new chemical substances of low concern before the end of the 90-day PMN review period. CMA also requested that EPA issue regulations establishing a procedure for handling individual section 5(h)(4) exemption applications.

In support of its petition, CMA argued that the requirements of section 5 of TSCA inhibit innovation in the chemical industry. According to CMA, the requested exemptions would significantly reduce the impact of section 5 on innovation and, by requiring review by an industry "qualified expert," encourage industry to conduct adequate risk assessments before introducing new chemical substances into commerce. CMA also stated that its proposal embodied a "pay as you go" approach. Under such an approach, PMNs on exempted chemical substances would be deferred until the cost of PMN submission would be less burdensome and until more comprehensive information developed by manufacturers might be available for EPA review.

EPA subsequently received petitions from the Synthetic Organic Chemical Manufacturers Association (June 28, 1981) and the Dyes Environmental and Toxicological Organization (July 10, 1981) requesting an exemption for the same categories of chemical substances proposed by CMA. In addition, seven trade organizations submitted endorsements of the CMA petition.

C. Alternatives Proposed

In response to the petitions from CMA and other groups, EPA began separate rulemakings for polymers and site-limited intermediates/low volume chemicals. This rule addresses only chemical substances produced at 1,000 kilograms or less per year. The polymer exemption rule was published in the **Federal Register** of November 21, 1984 (49 FR 46066).

After reviewing comments from both industry and the public, EPA has decided not to pursue at this time a rule to exempt site-limited intermediates and chemical substances produced in quantities of between 1,000 and 10,000 kilograms per year. Industry commenters stated that the exemption criteria for these categories (particularly the qualified expert provisions) were overly burdensome, and that the exemption did not provide significant relief. The Agency, however, determined that it could not reduce the procedural safeguards in the rule and still make the finding of no unreasonable risk. At the same time, public interest groups questioned the legal basis of the exemptions. Therefore, EPA has decided to issue a more limited exemption applying only to substances produced at 1,000 kilograms or less per year.

EPA also has decided not to pursue at this time a rule to shorten the PMN review period, because (1) it believes that the exemptions for low volume chemical substances and polymers will substantially reduce or eliminate the need for this exemption, and (2) there is a serious question as to whether TSCA permits EPA to allow early manufacture by either a rule or a policy statement. In addition, because of limited resources, EPA has decided not to develop general section 5(h)(4) procedural rules at this time.

II. Final Exemption

A. Summary of the Rule

The final rule exempts certain low volume chemical substances from premanufacture notification requirements of section 5 of TSCA. The basic outline of the rule is described below.

Manufacturers or importers of a new chemical substance produced at 1,000 kilograms or less per year may submit a brief exemption notice to EPA, in lieu of a full PMN, 21 days before manufacture. The notice must include chemical identity, a description of use, site of manufacture, and test data in the submitter's possession or control. EPA will review the notice and declare a chemical substance ineligible for the exemption if the Agency determines that the substance (or metabolites, environmental transformation products, impurities, or byproducts) may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal, or that serious unresolved issues concerning potential risks require further review. If EPA does not find the substance ineligible, manufacture may begin at the end of the review period. Manufacturers must submit another exemption notice before use or site or manufacture changes; only one manufacturer may make a given chemical substance under this exemption.

The rule also establishes procedures by which EPA can revoke an exemption for a specific chemical substance after manufacture has begun. EPA will revoke an exemption if new information indicates that the chemical substance does not meet the criteria for an exemption.

B. Discussion of the Final Rule

The final rule adopts most of the provisions concerning substances manufactured at 1,000 kilograms per year or less in the proposed rule published on August 4, 1982. This unit of the preamble clarifies several areas of confusion identified by public commenters and discusses the differences between the final rule and the proposal.

1. Scope of Rule

As explained in Unit I.C of this preamble, this final rule does not include exemptions for site-limited intermediates or substances produced at between 1,000 and 10,000 kilograms per year. It exempts from the full PMN requirements only certain substances produced in quantities of 1,000 kilograms or less per year.

2. Length of Review Period

The proposed rule would have required that companies notify EPA 14 calendar days before manufacturing a new chemical substance under the exemption. In the final rule, companies are required to notify EPA 21 calendar days before manufacture begins.

EPA recognizes that one of the major benefits of this exemption is that it allows companies to respond more rapidly to market demand and to introduce new chemical substances more quickly into commerce. Extending the review period from 14 to 21 calendar days will to a certain extent reduce this benefit. However, after carefully reviewing public comments and its experience in the premanufacture notice review process, the Agency has concluded that 14 calendar days will not be long enough to review exempt chemical substances adequately. Instead, 21 days is the minimum reasonable period in which EPA can review an exemption candidate and, if necessary, inform the manufacturer that it is not eligible for the exemption. For this reason, the review period was extended.

3. Exclusions

EPA will exclude specific substances from the exemption if, during its 21-day review, it concludes that the substances themselves, or reasonably anticipated metabolites, environmental transformation products, byproducts, or impurities, may cause serious acute or chronic effects in humans or significant environmental effects under reasonably

anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal.

Several commenters asked for clarification of these standards.

a. *Serious acute or chronic human effects.* Several commenters asked for further explanation of the standard for excluding chemical substances capable of causing "serious acute effects" and "serious chronic effects." To clarify this standard, EPA has revised these definitions to include "disfigurement" and "severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities," as well as death and severe or prolonged incapacitation. This revised definition would include any generally recognized adverse health effect (e.g., neurotoxic effects, liver and other organ toxicity, reproductive toxicity, mutagenicity, carcinogenicity, teratogenicity, fetotoxicity, skin sensitization, and severe skin and eye irritation). The modification makes it clear that a chemical substance could be excluded because of potential for non-life-threatening as well as life-threatening effects.

Several commenters also requested that EPA clarify the list of examples of serious acute or chronic effects contained in the preamble to the proposal. EPA intended that the list illustrate the kinds of possible effects that might cause the Agency concern and that could disqualify a substance from the exemption. EPA does not expect that exempt substances will not have any of these effects under any circumstances. However, if EPA concludes that a substance may cause any of these effects, the substance would not be eligible for the exemption unless the conditions of manufacture, processing, use, and disposal were such that serious adverse effects would not occur.

b. *Significant environmental effects.* The proposal defined "significant environmental effects" as "injury to the environment which reduces or adversely affects the productivity, utility, value, or function of biological, commercial, or agricultural resources, or causes the loss of a member of a rare or endangered species." The Agency received numerous comments on this definition, many of them expressing the concern that potential for any injury would lead to the exclusion of a substance from the exemption. Also, several commenters stated that the manufacturer might have no way to know whether the substance might threaten a single member of an endangered species.

In response to these comments, § 723.50(b)(11) of the final rule defines "significant environmental effects" as:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society,

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year, or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. "Endangered" or "threatened" species are those species identified by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

This change is intended to clarify the point that potential for insignificant or trivial injury to individual environmental organisms or to environmental resources would not disqualify a substance. As EPA explained in the preamble to the proposed rule, it does not intend to exclude all chemical substances that might cause any harm to any organism. Rather, the exclusion is directed toward "significant" environmental effects, both acute and chronic. The significance of environmental effects must be viewed in terms of the extent of the environmental damage, the potential recovery or repairability of the damage, and the degree to which the damage will impair the utility or function of the environmental unit affected.

Examples of significant environmental effects include direct effects on resources of demonstrable value, such as a fish kill reducing the value of a commercial fish population for a single generation, or a long-term reduction in a fish population over several generations. They also include indirect effects, such as long-term reduction in soil fertility; ecologically significant changes in species' interrelationships, e.g., excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems; and ecologically significant interference with critical biochemical cycles, such as the nitrogen cycle. This list is illustrative and is not intended to be all-inclusive. However, any substance capable of exhibiting these or comparable effects under reasonably anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal would not be eligible for an exemption.

Several commenters suggested that EPA modify the definition of significant environmental effects so that it was the same as the definition of substantial risk in EPA's policy statement implementing section 8(e) of TSCA published in the **Federal Register** of March 16, 1978 (43 FR 11110). Section 8(e) of TSCA requires manufacturers, processors, and distributors to notify EPA of any information that reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. However, EPA decided not to adopt the section 8(e) standard in this exemption; this standard was developed to ensure that EPA learned of known hazards associated with existing chemicals likely to be distributed widely in the environment. The Agency does not believe that this standard would be adequate to support a "no unreasonable risk" finding under TSCA section 5(h)(4). However, it should be clear that any environmental risk that would trigger a section 8(e) substantial risk notification would exclude a substance from this exemption if EPA concluded that such risks may occur under reasonably anticipated conditions of manufacturing, processing, distribution in commerce, use, or disposal.

c. *Byproducts and impurities.* The proposal excluded chemical substances from the exemption if there was a reasonable basis to conclude that byproducts of manufacture, processing, distribution in commerce, use, or disposal may have serious acute or chronic effects in humans or significant environmental effects under reasonably anticipated conditions of exposure. The final rule also excludes chemical substances if EPA concludes that impurities in the substance may cause such effects under reasonably anticipated conditions of exposure. This requirement was added because on several occassions the Agency has taken action on new chemical substances because of impurities. Therefore, EPA believes that it is necessary to consider impurities in its review and to exclude new substances because of potential risks posed by impurities.

4. Information Requirements

The final rule retains the basic requirements concerning the information the manufacturer must provide in the exemption notice. However, it modifies the requirements for chemical identity and use descriptions. These changes are discussed below.

a. *Test data.* Companies intending to manufacture a substance under the exemption must include test data in the submitter's possession or control that are related to the effects of the chemical substance on health and the

environment. This includes physical-chemical properties and environmental fate data relevant to risk assessment (e.g., vapor pressure, partition coefficient, biodegradation data) as well as toxicological data. Where a company performs tests to support an exemption, EPA recommends that it follow the testing guidelines developed by the Organization for Economic Cooperation and Development or EPA's Office of Toxic Substances (see EPA, "Health Effects Test Guidelines," EPA 560/6-82-001).

The term "possession or control" was defined in § 720.3(y) of the final PMN rule (48 FR 21722). However, that provision was stayed in the **Federal Register** of September 13, 1983 (48 FR 41132) and a new definition has been proposed in the **Federal Register** of December 27, 1984 (49 FR 50201). Until the new definition becomes final, exemption notice submitters should follow the September 13, 1983 clarification (48 FR 41132) and the preamble to the proposed definition (49 FR 50201).

b. *Data on impurities.* In the proposed rule, manufacturers were not required to provide EPA with any information on impurities. This information, however, is required in notices submitted under section 5(a)(1) of TSCA as part of the description of chemical identity. On several occasions it has proved critical in the Agency's assessment of risks posed by a new chemical substance. Therefore, EPA believes that it is necessary to require information on impurities in the final exemption rule. Section 723.50(e)(1)(iii)(D) of the final rule requires the manufacturer to identify impurities anticipated to be present in the exempt substance and their weight percent in the total substance. If there are unidentified impurities, the notice must include an estimate of their total weight percent. Information on impurities must be provided to the extent that it is known to or reasonably ascertainable by the submitter.

c. *Polymer identity.* The final rule has also been revised so that information required on polymer identity is the same as that required in § 720.45 of the PMN rule. To the extent the information is known or reasonably ascertainable, companies must indicate the typical composition of each monomer and other reactants used in the polymer (by weight percent of total monomer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram. The notice must also provide estimates of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight, and it must describe how the estimates were made. In the section 5 notice review program, EPA has frequently found this information important in assessing new polymers and in characterizing their potential risks. For this reason, EPA believes that such information is necessary in exemption notices as well as in section 5(a)(1) notices.

For guidance on providing information on polymer identities, companies should refer to EPA's clarification of the PMN notification requirements (48 FR 41132).

d. *Generic name.* In the proposal, there were no provisions for developing generic chemical names to protect confidential chemical identities. However, EPA intends to publish the identity of chemical substances manufactured under the exemption (see unit III.D of this preamble); therefore, the final rule requires manufacturers of exempt chemical substances to develop and submit to EPA generic chemical names masking the identity of the substance if they claim the substance's specific identity as confidential. The name must be only as generic as necessary to protect the confidential chemical identity and should reveal the specific chemical identity to the maximum extent possible.

It is important for manufacturers who claim chemical identity confidential to provide generic names; if a generic name is not provided, EPA may develop its own name and publish it on the list of exempted chemicals. This name may be less acceptable to the manufacturer than one it could have developed. For further discussion of generic names and confidentiality, see Unit II.B.10 of this preamble.

e. *Description of use.* In the proposal, manufacturers of low volume chemical substances would have been required to provide a brief use description by function and application in their exemption notices. Examples of function/application use descriptions are: Surfactant in automobile spray wax, colorant for paper and other cellulosics, and antioxidant in fuel oils and lubricants.

Section 723.50(e)(1)(iv) generally retains this requirement and further specifies that the submitter must indicate whether the use or uses are industrial, commercial, or consumer. However, the final rule drops the requirement that the use description "must be specific enough to indicate the typical circumstances of exposure, including routes of exposure, associated with new chemical substances." This sentence raised concern among commenters, some of whom believed it implied the need for extensive and detailed descriptions. EPA eliminated it from the final rule because it believes that a description of use by function and application will generally provide enough information to determine circumstances of exposure. However, when EPA does not have sufficient information on use to characterize exposure, the exemption may be denied if warranted by toxicity concerns.

The use description requirements in the final rule are consistent with those of the TSCA section 5(a)(1) notice form for new chemical substances. For guidance on developing use descriptions, or on providing other information in the exemption notice, such as chemical indentity, see the EPA "Instructions Manual for Premanufacture Notification of New Chemical Substances," available from the Office of Toxic Substances, TSCA Assistance Office, and EPA's **Federal Register** notice clarifying the PMN rule (48 FR 41132).

Several commenters suggested that use descriptions should be required only if the uses are known to the manufacturer. This suggestion was not adopted in the final rule. EPA believes that it is reasonable to require manufacturers, as a condition of the exemption, to ascertain the uses to which their products will be put and to provide that information to EPA. Because the use must be described only in relatively general function/application terms EPA believes that this requirement will not be burdensome.

f. *Exposure and other data.* Companies intending to manufacture a substance under this exemption are not required to provide information on exposure or exposure controls. However, they should recognize that EPA, without specific information on exposure, release, and controls will make reasonable assumptions, based on use, in reviewing the substance. Where there may be some concern for toxicity, manufacturers may wish to provide EPA with more information on exposure, release, or controls. In many cases, this information may eliminate potential EPA concerns. However, § 723.50(e)(1)(viii) requires that, where a manufacturer provides information on exposure controls or other controls to support its exemption notice, the manufacturer must maintain those controls throughout the exemption.

g. *Sanitized copy of notice.* The final rule requires the submitter to provide a sanitized copy of the notice. This provision, while not in the original

proposal, is included in the final rule to safeguard the confidentiality of the submission. This sanitized copy submission requirement is similar to requirements contained in the PMN rule (40 CFR 720.30(b)(2)), the polymer exemption rule (40 CFR 723.250), and the exemption rule for substances used in or for the manufacture or processing of instant photographic and peel-apart film articles (40 CFR 723.175).

5. Customer Notification

The proposal and the final rule require companies holding an exemption to submit a new exemption notice before manufacturing the exempt chemical substance for a use not described in the original notice. (This would include changes from one class of use to another—e.g., from industrial to consumer uses—as well as changes in function/application within these classes.)

Several commenters stated that this requirement raised difficulties because companies might not know of new uses developed by their customers. One commenter—an industry trade association—suggested that EPA could address these difficulties by requiring the manufacturer to notify customers of use restrictions. Section 723.50(j) of the final rule adopts this suggestion. The rule does not specify how companies must notify customers of use restrictions, but rather leaves the form of notification up to the exemption holder. However, as part of the rule's recordkeeping requirements (see Unit II.B.7 of this preamble), manufacturers are expected to keep records documenting notification.

EPA believes that this requirement is necessary because EPA's 21-day review will be based on the use description in the exemption notice. A change in use may lead to substantially different conditions of exposure. Therefore, EPA believes that it is appropriate to require the manufacturer to take reasonable steps to ensure that the exempt substance is used as intended (and as reviewed by EPA).

6. Notification of Changes in Site of Manufacture or Use

The proposal would have required manufacturers to renotify EPA if they manufactured a new chemical substance at a site of manufacture or for a use not reported in the exemption notice. Several commenters suggested that this requirement was unnecessary. Site of manufacture and use, however, will be important elements in EPA's 21-day review; changes in site or use might lead to considerably different exposure. Therefore, EPA believes that it is necessary to retain the requirement that companies submit a new exemption notice before either of these elements changes.

Several commenters suggested that it would be unnecessarily burdensome to comply with these renotification requirements. EPA, however, believes that the burden should be minimal. EPA assumes that submitters will be able to identify likely sites of manufacture and uses with reasonable accuracy in their original notices. Therefore, companies will have to renotify EPA infrequently.

7. Recordkeeping

The proposed rule required manufacturers to maintain records pertaining to production volume for 5 years after the final date of manufacture of the exempt substance. Many commenters pointed out that this requirement could mean that records might have to be retained almost indefinitely; commenters also suggested that this requirement was particularly difficult for production volume records, which are typically kept for only 5 years.

In response, EPA has modified the recordkeeping requirements. Section 723.50(o)(1) of the final rule requires manufacturers of exempt chemical substances to maintain production volume records for 5 years after the date of their preparation. In other words, exemption files must include production volume records for the previous 5 years. Manufacturers must also maintain (1) documentation of information in the exemption notice, and (2) documentation of compliance with the terms of the exemption. Documentation of compliance includes available records documenting site of manufacture and uses, customer notifications, etc. Like the production volume records, documentation of information in the notice and of compliance must be retained for 5 years after its preparation.

8. Standards for Denial of Exemption

The proposal stated that EPA would deny an exemption for a chemical substance during its abbreviated review if "the new chemical substance does not meet the terms of this section, or [if] unresolved issues concerning toxicity or exposure require further review." Several commenters suggested that it was inappropriate for EPA to deny an exemption simply because of "unresolved issues"; EPA should deny an exemption only when there was clear evidence that a substance was not eligible.

EPA disagrees with this comment and is retaining the proposed language in §723.50(g)(1) of the final rule, with minor editorial modifications. EPA has based its "no unreasonable risk" finding in part on its experience in the PMN process, which indicates that within 2 to 3 weeks of notice submission it can identify problematic chemical substances requiring more detailed review. In some cases, such substances are selected for more detailed review because of "serious unresolved issues," rather than because of affirmative evidence that a substance may be a problem. EPA believes that its ability to deny an exemption for the same reasons is an essential element of the rule and the no unreasonable risk finding.

EPA would not deny an exemption under this standard simply for speculative reasons. Instead, exemptions would be denied where serious concerns were raised, and more time or information was necessary to address them. For example, a chemical substance might be an analogue of a suspected carcinogen, or it might raise other toxicity concerns, but the potential for exposure might be unclear. This would be a particular concern where limited information was provided by the notice submitter or exposure fell outside the control of the manufacturer. In such cases, further review might be necessary to ensure that the manufacture and use of the exemption candidate would be safe.

In some cases, the submitter may be able to provide EPA with information during the 21-day review period that would resolve an issue, and manufacture would not be delayed. However, where a serious issue concerning the safety of the chemical substance cannot be resolved during the review period, it is important that EPA have the authority to reject the exemption.

9. Revocation

The proposal established procedures by which EPA could revoke an exemption for a given chemical substance after the review period ended. EPA would take such an action if new information indicated that the substance did not meet the terms of the exemption.

In general, EPA has retained the basic approach of the proposal, although it has modified the specific terms in several respects. Under the final rule, if EPA makes a preliminary determination that the substance does not meet the terms of the exemption after the review period has ended, it will notify the manufacturer by certified letter. EPA might reach this conclusion if new information indicated that the substance was not eligible (e.g., new data might be received on the exempt substance

showing significant risk potential). The manufacturer will have 15 days from written notification to submit objections to the determination or an explanation of its diligence and good faith in attempting to meet the terms of the exemption. If the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and submits objections or an explanation or both within 15 days, it may continue to manufacture, process, distribute in commerce, and use the substance while EPA considers the objections or explanation.

If a manufacturer is not manufacturing, processing, distributing in commerce, or using the chemical substance at the time it receives notification from EPA, it cannot resume manufacture until EPA determines that the substance meets the terms of the exemption or until a PMN has been submitted and the notice review period has ended without action by EPA.

This provision modifies the proposal which would have allowed the manufacturer to continue commercial activities after notification only if it were manufacturing the substance at the time of notification. Several commenters on the proposal suggested that these standards were unfair to batch processors who might not be in production at the time they received a notice of ineligibility. EPA believes it has addressed this problem by expanding the provision to allow manufacture to continue if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification. Thus, a batch manufacturer would not be adversely affected if it is between batches but still processing, distributing, or using the chemical substance previously produced. Although some companies will still be at a disadvantage under this approach, EPA believes that ineligible chemical substances should not be manufactured under an exemption. For this reason, the Agency believes that it is inappropriate to allow companies to begin manufacturing a substance under an exemption after information has been received indicating the substance is not eligible. The costs associated with this requirement should be minimal, because revocation procedures will probably have to be invoked only infrequently.

Several commenters stated that a 15-day period is not adequate to allow objections to be filed. In the final rule, EPA has modified this provision somewhat, requiring a response within 15 days of written instead of telephone notification. In its written notification, the Agency intends to provide specific questions about the substance's eligibility, so that the manufacturer will be able to respond to EPA's particular concerns. EPA believes that 15 days is adequate time for the manufacturer to submit objections and/or an explanation of its due diligence and good faith efforts to meet the terms of the exemption.

Under the final rule, like the proposal, EPA will respond to the manufacturer's objections and explanations within 15 days. If EPA determines that the substance meets the terms of the exemption, the manufacturer could continue or resume manufacture under the exemption. If EPA determines that, while the substance does not meet the terms of the exemption, the manufacturer acted with due diligence and in good faith to meet the terms of the exemption and the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification, the manufacturer may continue to manufacture, process, distribute in commerce, or use the substance if it submits a PMN under section 5(a)(1) of TSCA and the PMN rule within 15 days of the final notification by EPA. If such a manufacturer were to continue to manufacture, process, distribute in commerce, or use the substance without submitting a PMN, EPA would bring an enforcement action.

If EPA determines that, despite the company's objections or explanation, the manufacturer did not act diligently and in good faith, the company must cease manufacture, processing, distribution in commerce, and use within 24 hours of telephone notification. This provision slightly modifies the proposal requirements for companies determined by EPA to be acting without due diligence or in bad faith. Under the proposal, such companies would have been required to cease manufacture within 24 hours of EPA's initial notification. Under the final rule, these companies may continue commercial activities if they file objections.

In determining whether a manufacturer exercised due diligence and good faith in attempting to comply with the rule, the Agency would consider many factors, and decisions would be made on a case-by-case basis as an exercise of the Agency's discretion. For example, a manufacturer would not be considered to have exercised due diligence and to have acted in good faith if it (1) deliberately falsified information in the exemption notice, (2) failed to provide relevant toxicity data on the new chemical substance in its possession or control to EPA, or (3) knowingly changed the uses described in the notice after beginning manufacture.

Action under this provision of the rule would not prevent EPA from using its authority to bring an injunctive action under section 17 of TSCA to prevent further manufacture, or, if the substance presents an imminent hazard, action under section 7 of TSCA. In addition, any manufacturer who failed to meet the terms of the exemption intentionally or who submitted false or misleading information would be subject to an enforcement action.

10. Confidentiality

Section 723.50(k) of the final rule specifies confidentiality procedures. These procedures are essentially the same as those in the proposal and in § 720.80 of the PMN rule. They take into account various requirements under the Act, including the need to provide nonconfidential information to the public, give EPA information it needs to respond to Freedom of Information Act requests, and allow persons to assert claims of confidentiality with minimum burden.

Under this exemption, a person may assert a claim of confidentiality for any information submitted to EPA. To do so, submitters must clearly indicate on the exemption notice or attached document (e.g., by circling, underlining, or bracketing) the information that they wish to claim as confidential. Only the information claimed as confidential should be identified as confidential. A submitter should not simply stamp "confidential" on the page which contains both confidential and nonconfidential information.

As discussed in Unit II.B.4.d of this preamble, § 720.50(k)(3) of the final rule requires that submitters provide a sanitized copy of the exemption notice in which all confidential information has been deleted. The final rule also requires submitters to develop and submit generic chemical names if they claim chemical identity confidential. (See Unit II.B.4.d.) In some cases, companies may develop a generic name that EPA believes is more generic than necessary to protect confidential chemical identity. In this case, EPA, using the procedures in § 720.85 of the PMN rule, will propose to the submitter a more specific name. If that name is unacceptable, the submitter must explain why EPA's name is not sufficiently generic to protect confidential chemical identity and propose an alternative. EPA

will publish the submitter's alternative name if it is acceptable. Otherwise, EPA will use for publication in the **Federal Register** the generic name it devised 30 days after giving notice to the submitter.

Sanitized copies of the exemption notices will be placed in the public file. The generic names will be maintained on a list of exempted substances, which EPA will update once a month. These updates will be published monthly in the **Federal Register** and periodically in the *TSCA Chemicals-in-Process Bulletin.*

III. Major Issues

A. Volume Limits for Low Volume Chemical Substances

The final rule retains the proposed 1,000 kilogram per year limit for low volume chemical substances, but as explained in Unit I.C of this notice, the final rule does not retain the greater than 1,000 kilogram per year production volume limit category.

EPA selected 1,000 kilograms per year because it is high enough to provide relief to a significant number of new chemical substances (approximately 20 percent of new chemical substances), while low enough to set a reasonable bound on possible risks. EPA is convinced that the safeguards built into the low volume exemption are adequate to protect against unreasonable risks at 1,000 kilograms per year, particularly with the extention of the review period to 21 days. Furthermore, the 1,000 kilograms or less per year limit was chosen because it is consistent with the volume trigger for full new chemical notification under the European Economic Community's Sixth Amendment.

B. Exclusion of High-Risk Chemical Categories

In the proposal, EPA suggested as an alternative that a list of high-risk chemical categories, based on structure, be developed. Individual new chemical substances falling into these categories would not be eligible for the exemption. The Dyes Environmental and Toxicology Organization, Inc. (DETO), in effect suggested this approach in its exemption petition for dyes when it stated that EPA might consider excluding benzidine,o-tolidine, and o-dianisidine-based dyes, and dyes containing N-N-dimethyl-4-aminobenzene analogues. The basis for this exclusion would be structure-activity information and test data which suggest that individual members of these categories might cause serious chronic health effects. Several commenters suggested that such an approach would be advisable and would significantly strengthen the exemption.

EPA did not adopt this approach because it would be unnecessarily resource-consuming to develop a list of excluded categories of chemical substances. EPA believes that any general list of categories would provide no more protection than that already provided in the proposed rule by EPA's 21-day review. New chemical substances belonging to highly suspect classes, such as the classes identified by DETO, would be eliminated unless exposure information provided by the submitter demonstrated their safety under conditions of manufacture and use.

C. Subsequent Manufacturers

Under the final rule, only one manufacturer is allowed to manufacture a given substance under the exemption. Subsequent manufacturers of the same chemical substance would not be eligible for the exemption; they would be required instead to submit a premanufacture notice. This requirement is necessary because the risk assessment for the exemption assumes that total production of chemical substances in the category will not exceed the production volume limit of 1,000 kilograms per year.

Several commenters on the proposal criticized this approach on the grounds that it could result in unwarranted administrative complexities and that it might delay manufacture. As an alternative, commenters suggested that EPA allow subsequent manufacture under the exemption. EPA would have the opportunity to review the exemption notice and revoke the exemption for all exemption holders if it identified any concerns.

EPA rejected this approach because it could allow the aggregate production volume to grow well beyond the low volume limit without full premanufacture review. The exemption is based on the premise that the exempted substances will in fact be low volume—that is, below 1,000 kilograms per year. Even though it appears relatively unlikely that second or third manufacturers would produce the same substance under a given low volume exemption, this possibility could theoretically lead to the production of an exempt substance at volumes many times greater than the exemption volume limit. Also, it would be possible for companies to circumvent the volume limit by buying an exempt substance from several different manufacturers or importers, yet the substance could still be processed or used at a single site. EPA does not believe that the 21-day review will be adequate to identify such situations consistently. For these reasons, EPA believes that it is inadvisable—and inconsistent with its risk assessment—to allow multiple manufacturers under the low volume exemptions.

EPA also believes that commenters have exaggerated the administrative complexities and potential for delay associated with the requirement that subsequent manufacturers of low volume substances submit a premanufacture notice. The rule establishes a system to allow companies with *bona fide* intent to manufacture a substance under a low volume exemption to determine whether their substance is already being manufactured under that exemption. EPA now operates a comparable *bona fide* system under the premanufacture notice program and finds it effective and workable. If manufacturers do not wish to face the delay associated with the *bona fide* process, they can submit an exemption notice; of another company is already manufacturing the substance under the exemption, the notice would be rejected. However, because this would happen only very rarely, it is likely that few if any manufacturers would be rejected on these grounds.

To simplify the administration of this rule, EPA will maintain a list of exempted substances and will have monthly additions to the exemption list published in the **Federal Register** and periodic updates in the *TSCA Chemicals-in-Process Bulletin.* As a result, prospective manufacturers of low volume substances may be able to determine whether a given substance is eligible for the low volume exemption. However, because substances will be listed under generic names when their identities are confidential, it may still be necessary for companies to make *bona fide* inquiries, or to submit exemption notices without absolute certainty that another company is not already making the substance under the exemption.

D. Public Notice

In the preamble to the proposal, EPA stated that exempt substances will not be added to the TSCA Chemical Substance Inventory because they have not undergone section 5 premanufacture review. As a result, the public would have no way of knowing which chemical substances were being manufactured under the exemption. This would reduce public knowledge concerning EPA's conduct of the exemption review process, and would make it difficult for chemical companies to determine if a particular chemical substance was being

manufactured under an exemption. Without a list of exempt substances, manufacturers would find it more difficult to ascertain whether a specific new chemical substance was already being manufactured under an exemption and therefore whether it was eligible for the low volume exemption.

For these reasons, EPA will maintain a list of substances that have cleared exemption review, and will publish updates to the names of the substances added to the low volume exemption list. These updates will appear monthly as notices in the **Federal Register** and appear periodically in the *TSCA Chemicals-in-Process Bulletin*. If the identity of a given chemical substance is claimed confidential, EPA will publish a generic chemical name supplied by the manufacturer, or one that it has developed as described in Unit II.B.10 of this preamble. In addition, EPA will maintain a low volume exemption public file comparable to the PMN public file. Sanitized versions of exemption notices submitted under this rule will be placed in the file. Companies are required to submit sanitized notices, with all confidential material deleted, together with any notices containing confidential business information.

Together, the published low volume exemption list and the public file will give the public a reasonable understanding of the scope of the program and the nature of the substances being manufactured under the exemption. They will also simplify procedures for companies intending to manufacture substances under the exemption.

IV. Regulatory Analysis

To support the August 4, 1982 proposal, EPA prepared a risk assessment and an economic analysis. After reviewing public comments, EPA revised these documents, modifying them where necessary to reflect changes in the final rule. The final documents are available in the public record of this rulemaking. The documents are summarized briefly below. This unit also explains the basis for the Agency's finding of no unreasonable risk.

A. Summary of Risk Assessment

1. General Approach

In its analysis of the risks posed by low volume chemical substances, EPA evaluated the risks that could be associated with toxic volume substances without the various restrictions or conditions that could be included in an exemption. This analysis provided an estimate of possible risks from such substances and a basis for determining whether or not specific safeguards would be needed. EPA then considered the impact of the exemption conditions to determine the extent to which they would reduce the risks. Although such reductions in risk were not readily quantifiable, EPA believes that the provisions of the exemption will reduce the risks estimated in the assessment so that unreasonable risks will not occur.

EPA's general approach in evaluating potential risks from low volume substances involved:

(1) Selecting hazards (i.e., adverse health and environmental effects) that are of concern in protecting human health and the environment.

(2) Determining a representative range of potencies for assessing each of the effects of concern.

(3) Defining exposure scenarios.

2. Low Volume Chemical Substances

a. *Analysis of potential health and environmental effects.* In analyzing low volume chemical substances, EPA selected a range of potencies for certain health effects for hazard evaluation. This procedure is justified by the fact that nothing inherent in low volume substances limits their toxicity. However, very few new low volume substances are likely to exhibit the upper ranges of toxicity represented in the risk assessment.

b. *Exposure assessment.* The exposure assessment illustrates that while low production volume in itself sets bounds on potential for exposure and environmental release, the manufacture, processing, and use of such substances can in some circumstances result in significant exposure.

i. *Occupational exposure.*—Low production volume typically limits the total number of workers who may be exposed to chemical substance, as well as the duration and frequency of exposure. However, the actual exposure levels for individual workers may be substantial. Based on PMN data, about four workers are exposed, on the average, during manufacture of chemical substances produced in quantities of 1,000 kilograms or less per year. Duration of exposure associated with manufacture averaged about 5 hours per day, and the average number of days of production per year was 62.

Only a limited number of PMNs included estimates of workplace concentration. The average concentrations associated with manufacture were most often in the ranges of 0–1 and 1–10 mg/m^3 for airborne solids and in the 1–10 ppm range for vapors. EPA's evaluation of Occupational Safety and Health Administration (OSHA) data (USEPA–OTS, "Site-Limited Intermediate Exemption: Occupational Exposure and Environmental Release Assessment," March 19, 1982) indicated an average TWA concentration of 0.14 mg/m^3, with a maximum value of 0.6 mg/m^3 for airborne solids, and an average TWA of 6 ppm, with a maximum value of 72 ppm for vapors. EPA believes that data obtained from OSHA monitoring activities provide more reliable estimates of workplace concentrations.

EPA's analysis indicated that processing and use operations may result in a higher level of exposure than manufacturing operations. Also, the average number of workers exposed during processing and use operations exceeded the average number typically exposed during manufacture. The number averaged 12 workers for a substance processed in quantities of 1,000 kilograms or less per year.

ii. *Consumer exposure.*—Consumer exposure was assessed for five use scenarios—photographic chemicals used in home darkrooms, spray adhesives, paints, dyes, and fragrances used in soaps, detergents, or shampoos. The use scenarios, which reflect actual uses reported in PMNs, were selected to represent a range of potential exposure situations.

According to EPA's analysis, the individual lifetime average daily exposures in these scenarios ranged from negligible levels for dyes in dyed fabrics to 0.0016 mg/kg/day for a fragrance in soap. Many of the scenarios could result in the exposure of relatively large numbers of consumers. At the 1,000-kg/yr production level the estimated number of consumers exposed ranges from 440,000 for a fragrance in shampoo to 26,000 for an additive in spray adhesives. Because the concentration of the substance in final products would remain constant, reduction in production volume is likely to reduce only the number of consumers exposed, not the exposure to each individual.

iii. *Environmental release.*—The exposure analysis indicated that the average quantity released to water is 0.08 percent of production volume, with an upper bound of 0.4 percent. However, some processing and industrial uses result in more substantial release rates with a range from 0.3 to 25 percent of the production volume released to water. Releases to air average 0.03 percent of production volume, with a 0.2 percent upper bound. Discharges of a new low volume substance from a single site processing 1,000 kilograms of the substance were estimated to produce

environmental concentrations ranging from <0.0005 to 0.53 ppm in a receiving stream whose stream dilution factor was equal to the national median for streams receiving effluents from industrial facilities.

In some cases, environmental releases from consumer uses equaled the total production volume. However, the actual magnitude of environmental exposure was determined to be insignificant because of the low production volume, the wide distribution of release, and the small amount of the new substance typically contained in consumer products.

c. *Estimated risks.* Given the above exposure and environmental release estimates, EPA evaluated the risks to workers, consumers, aquatic organisms, and persons living near a plant manufacturing or processing low volume chemical substances.

Although EPA expects that most low volume substances will present low risks, the assessment illustrated that workers could be subjected to significant health risks from potent or moderately potent carcinogens, teratogens, neurotoxins, or reproductive hazards. Airborne concentrations of low volume substances appear to present negligible risk to general populations, except when the released substance is a highly potent carcinogen or teratogen. Aqueous releases that may contaminate drinking water also appear to present low risks, except where the released substance is a highly potent toxic agent or where direct discharge occurs at the maximum release estimated by EPA.

Consumer exposure under most of the scenarios considered appears to present significant risks if the new substance is at least a moderately potent carcinogen. In addition, potent and moderately potent teratogens, neurotoxins, and reproductive hazards might also present substantial risks.

Environmental risks from most low volume substances would not present substantial risks to aquatic organisms at estimated discharge rates. However, EPA's analysis also demonstrates that it is reasonable to expect that a small number of substances may present substantial risks to aquatic organisms at anticipated high stream concentration levels.

d. *Chemical substances manufactured at 1,000 kilograms or less per year.* For chemical substances manufactured at 1,000 kilograms or less per year, fewer workers and consumers (than those associated with higher production volumes) are likely to be exposed. Actual exposure at this level of production will in most cases be substantially less than that indicated in the exposure analysis, which is based in part on available data from relatively large scale operations.

For small scale operations to reach the workplace exposure indicated in the exposure assessment, production of the total 1,000 kilograms generally would have to take place in a relatively short time— perhaps as short as a day or two. In this case, the duration of exposure would be low, and therefore the potential for adverse chronic effects would be significantly reduced. Where manufacture took place over a relatively long period, workplace exposure would be unlikely to reach the levels identified in the exposure assessment (USEPA–OTS, "Site-Limited Intermediate Exemption: Occupational Exposure and Environmental Release Assessment," March 19, 1982).

Small volume operations are typically conducted over an extended period only if there is a need for careful control (for example, to ensure product purity); this control would be likely to reduce exposure. Because of the small daily production volume, the small size of equipment, and the localized nature of operations, effective control is possible, and environmental release and exposure to the worker from activities such as material transfer, sampling, and cleanup is minimized.

In addition, substances produced at 1,000 kilograms or less per year will not typically receive wide distribution. In many cases, they are produced for limited purposes or do not achieve commercial success and thus do not remain on the market long. Therefore, widespread or long term exposure to commercial users or consumers is unlikely.

3. Risk Under Exemption Conditions

There are several elements of the exemption that will substantially reduce the risks to human health and the environment identified in the risk assessment. The most important of these elements are the low risk associated with low volume and the 21-day EPA premanufacture review.

The basis for low risk associated with low volume is the inherent expectation of low exposure potential because of the small quantities being manufactured. Risk will be reduced by the exclusion from the exemption of chemical substances where EPA determines that they may cause serious human or environmental effects under conditions of manufacture, processing, distribution in commerce, use, and disposal.

EPA's 21-day premanufacture review for all chemical substances manufactured under this exemption will exclude from exemption those chemical substances that fail to meet these standards, and will provide a level of protection equivalent to that now provided in the PMN program.

B. Summary of Economic Analysis

1. Introduction

To perform the economic analysis of the low volume exemption, the Agency created a data base from a sample of about 500 PMNs which represented the total submitted during a specific period in 1980 and 1981. This data base provides an overview of the Agency's experience with the PMN program. The Agency reviewed this data base to determine types of chemical substances being submitted for review, their projected production volumes, their intended uses, and in some cases their potential toxicity. This information was used to estimate the number of new substances that would be likely to be eligible for an exemption.

The Agency also reviewed the current cost of PMN requirements for manufacturers of new low volume substances; it estimated the direct relief to industry, reflected in decreased reporting costs and decreased time in bringing a new substance to the market, that would result from different exemption alternatives. It estimated direct savings to EPA resulting from decreased PMN review costs. These figures were used to derive quantitative estimates of benefits.

In assessing benefits, EPA also considered nonquantifiable benefits, such as increase in chemical innovation. Although the Agency could not attach specific figures to these benefits, they are likely to be substantial. EPA's analysis of the impact on industry of the PMN rule suggests that the nonquantifiable costs of the program may be greater than the quantifiable costs. By extension it appears reasonable to assume that the nonquantifiable benefits of an exemption may be greater than those that can be quantified.

The complete economic analysis consists of an economic support document and a supplemental memorandum and can be found in the public file.

2. Current Impact of PMN Program

As a baseline for its economic analysis, EPA estimated the annual direct costs of submitting PMNs on low volume substances. A review of the sample of 500 PMNs indicates that about 21 percent of all PMNs (210 out of the annual submission rate of 1,000 PMNs) are substances produced in quantities of

1,000 kilograms or less per year. Using the current PMN reporting costs, the annual reporting costs to industry for low volume substances can be estimated to be between $273,000 and $1,575,000.

Besides these direct filing costs, industry is also faced with additional costs from the TSCA-imposed 90-day PMN review period (delay costs), from having to assert and possibly substantiate confidential business information claims, and from uncertainty.

3. Benefits of the Exemption

The Agency estimated the number of new chemical substances that would be eligible for the exemption by counting the number of chemical substances for which there are PMNs that fall under the exemption. From this number, EPA then calculated the annual net benefits of the exemption. These benefits include the actual cost savings to industry for not having to submit PMNs and the savings from the reduction of the 90-day delay. The costs of having to submit the exemption notices are subtracted from the gross savings to obtain the net savings to industry.

Assuming a rate of 1,000 PMNs a year, the low volume exemption would exempt about 210 new substances per year; net benefits to industry would be between $460,000 and $1,450,000 or between $2,190 and $6,905 per exempted chemical. The "low" end of the net benefits range was based on the lowest estimates of the cost to submit a PMN; the "high" end of the benefits was based on the highest estimates of these figures. This cost figure also includes the discounted costs of submitting a PMN in the third year for chemical substances whose production volume would exceed the volume limit by the third year of production.

The economic analysis also indicates that the exemption may lead to direct savings in EPA resources that would otherwise be spent reviewing PMNs. For low volume chemical substances, the saving would be $19,000, or $91 per exempted chemical. These figures reflect the difference between costs of reviewing a PMN and estimated costs of reviewing an exemption notice. Of course, EPA resources would not be freed if the availability of the exemption led to an increase in innovation and a significant increase in the overall number of submissions to EPA.

In addition to the benefits which EPA has quantified, there are certain benefits which the Agency has examined qualitatively. Chief among these are the benefits of reduced uncertainty and of increased innovation. The reduction in the length of the review period from 90 to 21 days would reduce the period of uncertainty about the outcome of EPA's review of the notice (whether the substance would be manufactured, when, and under what restrictions, if any, etc.). Also, by reducing direct PMN filing costs and delay costs, the exemption will encourage chemical innovation. These reductions will mean that substances which formerly were not profitable to introduce would not be acceptable investments. The net value of this additional innovation would constitute additional benefits, both to the chemical industry and to society.

C. Finding of No Unreasonable Risk

1. Statutory Background

Under section 5(h)(4) of TSCA, EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to health or the environment. Section 26(c) of TSCA provides that any action authorized under TSCA for an individual chemical substance may be taken for a category of such substances.

The term "unreasonable risk" is not defined in TSCA. The legislative history indicates that determination of whether a risk is unreasonable requires a balancing of the probability and severity of harm from the substance or category of substances against the cost of the regulatory action to society. Because EPA's determination of the reasonableness of risk involves a consideration of factors such as environmental effects, use patterns, and market potential, which are frequently difficult to define and quantify precisely, EPA must rely not only on the available data but also its professional judgment. Congress recognized that the implementation of the unreasonable risk standard "will vary depending on the specific regulatory authority which the Administrator seeks to exercise." [Legis. Hist. at 422]

2. EPA's Approach To Making the No Unreasonable Risk Finding

To determine whether the category of substances manufactured under the exemption presents an unreasonable risk, the Agency should consider not only the inherent risks presented by the overall exemption category, but also the extent to which specific exclusions or adjustments of the overall category definition have mitigated such potential risks. EPA must then analyze the effect on risk of any further conditions imposed on the exemption. For example, manufacturers who intend to use the exemption must submit only a limited notice, which may affect the Agency's ability to identify risk. Because the effect of the exemption is to modify general PMN requirements, EPA should also compare the absolute risk posed by the same substances if the substance had been subject to the full notice submission requirements and minimum 90-day EPA review period.

Congress did not intend the section 5 review process to eliminate entirely all risk resulting from manufacture, processing, distribution in commerce, use, and disposal of new chemical substances, nor is it possible to do so. While section 5 gives EPA the opportunity to review all new chemical substances, the Agency is authorized to ban such substances or otherwise control against risks only (1) when it can show that the substances will present an unreasonable risk of injury to health or the environment (section 5(f) of TSCA), or (2) when there is insufficient information to evaluate the risks and EPA finds either that the manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk, or that the substance will be produced in substantial quantities and will be released in substantial amounts or will result in significant or substantial human exposure (section 5(e) of TSCA). To the extent that certain risks presented by members of a category of substances would not have been regulated by EPA during a full PMN review, assuming EPA's maximum exercise of its section 5 authorities, such risks could not be considered to be risks posed by an exemption rule.

There are two methods of calculating the benefits of the exemption which should be weighed in determining whether exempt substances will present an "unreasonable" risk. First, EPA can consider the benefits in a manner analogous to the way it would consider them if the Agency were evaluating a particular member of the category during an ordinary PMN review. Under this approach the evaluation would focus on the benefits of the substances to society, and the extent to which any regulation of the substances necessary to address risk concerns would reduce or eliminate such benefits. The basis for considering this type of benefits information is that Congress arguably did not intend to exempt from premanufacture notice requirements any substances which were likely to have been subject to control under section 5(e) or 5(f). EPA thus would not consider

the reduced burden of the PMN or other benefits of reducing PMN requirements, because these costs would not be considered in making a regulatory decision on a PMN substance. One problem with focusing on the benefits of the substances in the category is that, while section 5(h)(4) contemplates granting exemptions by category, it is difficult or impossible to predict accurately the nature of those benefits.

Under the second approach, EPA could consider benefits beyond those considered in an actual PMN review. As discussed in the proposed rule, a broader consideration of benefits would analyze, in addition to the benefits of the substances themselves, the reduction in the costs to society imposed by the full PMN requirements. There are strong arguments for taking such an approach in making a no unreasonable risk finding in the context of a section 5(h)(4) exemption. The legislative history indicates that EPA's unreasonable risk consideration should include effects on society beyond the benefits of a substance. In addition, unlike the review of an individual PMN, the costs of PMNs for substances which would be addressed by this exemption have not already been paid. Such direct costs would include the cost of preparing and submitting the PMN, and the cost of the delay in the introduction of the benefits of a new chemical. In addition, economic analyses have indicated that reporting and delay costs may discourage the introduction of new chemical substances. While elimination of these costs would not be a benefit that EPA would take into account in making an individual control decision on a new substance, they are real effects on society which result from EPA's exercise of its exemption authority and are thus appropriately considered in a section 5(h)(4) unreasonable risk finding for a category of substances.

3. Exemption Conditions

There are several exemption provisions that directly or indirectly reduce the likelihood that exemption substances would adversely affect health or the environment. EPA believes that these provisions together will significantly limit risk and will adequately support a finding of no unreasonable risk, given the bounds on exposure associated with the exemption category and the benefits of the exemption.

The major provisions that limit risk are discussed below:

a. *Production volume limitation.* A critical element of the finding is that low volume chemical substances manufactured in volumes of 1,000 kilograms or less per year have limits on exposure potential. The number of workers exposed and the duration and frequency of exposure is generally limited. Uses would be for the most part limited to specialty applications, and consumer exposure would not typically occur. Under some circumstances, significant numbers of consumers could be exposed, but the levels of exposure would usually be low.

b. *EPA review.* EPA's abbreviated review plays an important role in the exemption and in the finding of no unreasonable risk. In the final rule, EPA has strengthened this review by lengthening it from 14 to 21 days. During this period, the Agency will have sufficient time to identify any problems that were likely to have been identified in a full PMN review. If EPA determines that a new chemical substance is not eligible for an exemption, manufacture cannot begin. The manufacturer is then required to comply with TSCA section 5(a)(1) before the substance can be manufactured for commercial purposes.

c. *New information and EPA revocation.* In addition to these safeguards, the rule contains several other provisions that will further limit the possibility that exemption substances will present significant risks. Most important, the rule establishes procedures for revocation of the exemption if EPA later determines that the substance does not meet the conditions of the exemption. In addition, EPA has the authority to require documents relevant to an exemption from the manufacturer (in addition to the information provided in the exemption notice), and the manufacturer is required to submit promptly to EPA any new data indicating that a substance is ineligible. These provisions will ensure that eligibility for the exemption will be determined on the basis of the best available information, regardless of when the information becomes available.

4. Benefits

It is impossible to quantify the total benefits which may accrue to society from the individual substances subject to this exemption. Uncertainty about benefits is inherent in any action under TSCA which deals with a category of substances whose structure and uses are unknown. However, it is clear that the field of chemistry has been the source of many recent technological advances, particularly in the area of low volume specialty chemicals. In addition, it is obvious that a new chemical substance must present benefits to society by performing a new function, or performing an old function more efficiently or less expensively, or with less risk, or it would not have been developed or used. Therefore, EPA has concluded that the new chemical substances eligible for exemption, as a category and as individual substances, will present some significant benefits to society.

EPA was able to quantify some of the benefits to society which will result from this exemption that do not depend on specific knowledge about the benefits of the individual substances. First, as is indicated above, manufacturers submitting notices under this exemption will incur reduced reporting costs. Second, there will be a potential for significant reduction in the delay in introducing new substances. Manufacturers, and the general public, will be able to take advantage of the benefits of individual new low volume substances more quickly, including any increases in efficiency and decreases in cost.

Assuming that approximately 210 new chemical substances a year would be manufactured under the exemption, net benefits would be between $46,000 and $1,450,000 annually. Of this amount, a significant portion consists of the savings in costs due to reduced delay. Total industry costs associated with the PMN program are presently estimated at $3.715 to $9.915 million annually. The final exemption rule will therefore reduce this cost to industry by about 12 to 15 percent.

5. Conclusion

Given the limitations on risk posed by substances manufactured under this exemption and the benefits that would be derived from them, EPA has determined that substances manufactured under the terms of this exemption rule will not present an unreasonable risk.

V. Judicial Review

To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA has decided to promulgate this rule for purposes of judicial review 2 weeks after publication in the **Federal Register**, as reflected in **"DATES"** in this notice. The effective date has, in turn, been calculated from the promulgation date.

VI. Record

EPA has established a record for this rulemaking (Docket Number: OPTS–50032) which is available for inspection in Rm. E–107, 401 M St. SW., Washington, D.C. 20460. Persons who do not have access to the record in the

public reading room should contact Edward A. Klein, Director, TSCA Assistance Office (TS-799), at the above address for assistance.

The record includes all information considered by the Agency in developing this exemption proposal. The preamble to the proposal lists items entered into the record through June 1982. The list below identifies items entered into the record after that date. These lists together identify the complete rulemaking record:

57. Adhesives Manufacturers Association. "Letter Endorsing the Chemical Manufacturers Association Petition for PMN Exemptions," August 13, 1981.

58. *USEPA–OTS.* "Letter from Edward A. Klein, Director, Chemical Control Division, to Bill Ahrens, Adhesives Manufacturers Association," September 14, 1981.

59. *USEPA–OTS.* "Premanufacture Notification: Proposed Exemption for Site-Limited Intermediate Chemical Substances Manufactured in Quantities of 10,000 Kg or Less Per Year," 47 FR 33896, August 4, 1982.

60. Comments received in response to proposed rule exempting certain new site-limited intermediates and low volume chemicals from premanufacture notice requirements, 47 FR 33896 (52 comments).

61. *USEPA–OTS.* "OTS–DETO Meeting Summary," Summary of meeting with Dyes Environmental and Toxicology Organization (DETO), Septemer 14, 1982.

62. *USEPA–OTS.* "Summary of Meeting with Brulin and Co., Inc.," October 4, 1982.

63. Transcript of public meeting on proposed rule exempting certain site-limited intermediates and low volume chemicals from premanufacture notice requirements, 47 FR 33986 (6 exhibits).

64. *USEPA–OTS.* "Questions for Participants in the Public Hearing," November 1, 1982.

65. Comments received in response to public hearing on proposed exemption for site-limited intermediates and low volume chemical substances (7 comments).

66. Chemical Manufacturers Association (CMA). "Supplemental Comments on Proposed Exemption Rule under section 5 (h)(4) of the Toxic Substances Control Act," March 21, 1983.

67. *CMA.* "Letter to Don R. Clay, Acting Assistant Administrator for Pesticides and Toxic Substances," June 2, 1983.

68. *USEPA–OTS.* "Response to Comments on Proposed PMN Exemption for Low Volume Chemicals," December 31, 1984.

69. Office of Management and Budget (OMB). "PMN Exemption Rules: Staff Option," November 7, 1983.

70. *SOCMA.* "Letter to William Ruckelshaus, Administrator of the Environmental Protection Agency," January 23, 1984.

71. *USEPA–OTS.* "Economic Impact Analysis of TSCA Section 5(h)(4) Exemptions: Low Volume and Site-Limited Intermediate Chemicals," September 1983.

72. *USEPA–OTS.* "Memorandum: Economic Analysis of the Final Exemption Rule for Low Volume Chemicals," Revising "Economic Impact Analysis of TSCA Section 5(h)(4) Exemptions, Low Volume and Site-Limited Intermediates Chemicals," October 26, 1984.

73. *USEPA–OTS.* "Risk Analysis in Support of the Proposed Exemption of Site-Limited Intermediates and Low Volume Chemicals," December 5, 1983.

74. *USEPA–OTS.* "Health and Environmental Risk Assessment of TSCA Section 5(h)(4) Exemption for New Low Volume Chemicals," revising "Risk Analysis in Support of the Proposed Exemption of Site-Limited Intermediate and Low Volume Chemicals," November 1, 1984.

75. USEPA–OTS. "Low Volume Exemption—Occupational Exposure and Environmental Release Assessment," March 1982.

76. USEPA–CTS. Memorandum "Engineering Assessment of the Final Exemption Rule for Low Volume Chemicals," October 30, 1984.

VII. Application of Executive Order 12291, Paperwork Reduction Act, and Regulatory Flexibility Act

This regulation does not satisfy any of the criteria for major regulation described in Executive Order 12291; therefore, EPA has determined that a Regulatory Impact Analysis is not necessary. The annual impact of the rule on the economy will not exceed $100 million; instead it will provide substantial relief to the regulated industry. The rule will not burden any particular geographic region and will not affect government agencies, except that it may reduce the burden of PMN review for EPA. The exemption will not adversely affect the ability of domestic manufacturers to compete with foreign manufacturers or vice versa and it will encourage chemical innovation. EPA expects that the net effect of this exemption rule on the economy will be positive.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA hereby certifies that this rule will not have a significant adverse economic impact on a substantial number of small businesses. Instead, it will provide relief from the burdens of the present PMN requirements, and is likely to be particularly beneficial to small businesses. The Chemical Specialties Manufacturers Association, which represents many small businesses, has stated that "declines in the rates of projected innovation as a result of TSCA costs were on the whole substantial, and were particularly heavy for firms in smaller size classes." Since the exemption will reduce PMN filing costs and shorten production delays, small manufacturers will especially benefit from the rule.

In addition, small firms will benefit because they submit a disproportionately large percentage of PMNs on low volume chemical substances. According to the PMN data base, 31 percent of the PMN submissions by small firms have been on substances with projected production volumes of 1,000 kilograms or less per year, while only 21 percent of all PMNs have been on such substances. Therefore, the low volume exemption is likely to provide proportionately greater relief to these small firms. For this reason, the Agency has not prepared a Regulatory Flexibility Analysis for this rule.

The information collection requirements contained in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070–0012.

List of Subjects in 40 CFR Part 723

Chemicals, Environmental protection, Premanufacture notification exemption, Hazardous substances, Recordkeeping and reporting.

Dated: April 19, 1985.

Lee M. Thomas,

Administrator.

PART 723—[AMENDED]

Therefore, Chapter I of Title 40 of the Code of Federal Regulations is amended by adding a new § 723.50, to read as follows:

§ 723.50 Chemical substances manufactured in quantities of 1,000 kilograms or less per year.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of certain chemical substances manufactured in quantities of 1,000 kilograms or less per year.

(2) To manufacture a new chemical substance under the terms of this exemption, (i) a manufacturer must submit a notice of intent to manufacture 21 days before manufacture begins, as required under paragraph (e) of this section; and (ii) the manufacturer must comply with all other provisions of this section.

(b) *Definitions.* (1) "Act" means the Toxic Substances Control Act (15 U.S.C. 2601 *et seq*).

(2) The terms "article," "byproduct," "EPA," "health and safety study," "importer," "impurity," "known to or reasonably ascertainable," "manufacture," "new chemical substance" "person," "possession or control," "test data" have the same meanings as in § 720.3 of this chapter.

(3) The term "Assistant Administrator" means the EPA Assistant Administrator for Pesticides and Toxic Substances or any employee designated by the Assistant Administrator to carry out the Assistant Administrator's functions under this section.

(4) The term "category of chemical substances" has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625(c)(2)).

(5) "Director of the Office of Toxic Substances" means the Director of the EPA Office of Toxic Substances or any EPA employee designated by the Director to carry out the Director's functions under this section.

(6) The term "environment" has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(7) "Environmental transformation product" means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(8) "Metabolite" means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(9) "Serious acute effects" means human disease processes or other adverse effects that have a short latency period for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(10) "Serious chronic effects" means human disease processes or other adverse effects that have a long latency period for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(11) "Significant environmental effects" means either:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society,

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year, or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. "Endangered" or "threatened" species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(12) "Site" means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site.

(c) *Exemption categories.* Any person who intends to manufacture (including import) a new chemical substance in quantities of 1,000 kilograms or less per year may seek an exemption under this section for that chemical substance, subject to the conditions specified in paragraph (d) of this section. No more than one person may hold an exemption for a particular new chemical substance under this paragraph.

(d) *Exclusions*—(1) *Chronic effects.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the substance or a reasonably anticipated metabolite or environmental transformation product of it may cause serious chronic effects, including carcinogenic and teratogenic effects, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(2) *Acute effects.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the substance or a reasonably anticipated metabolite or environmental transformation product of it may cause serious acute effects (lethal or sublethal) under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(3) *Environmental effects.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the new chemical substance or a reasonably anticipated environmental transformation product of it may cause significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(4) *Impurities.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that reasonably anticipated impurities in the substance may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(4) *Impurities.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that reasonably anticipated impurities in the substances may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(5) *Byproducts.* A new chemical substance cannot be manufactured under this section if EPA determines, in accordance with paragraph (g) of this section, that the reasoanbly anticipated byproducts of manufacture, processing, distribution in commerce, use, or disposal of the substance, including waste or emissions, may cause serious acute or chronic effects in humans or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance.

(e) *Exemption notice.* (1) The manufacturer must submit a notice to the Document Control Officer as provided in paragraph (n) of this section at least 21 days before manufacture begins. The date of submission will be the date on which the notice is received by the Document Control Officer. EPA will acknowledge the receipt of the notice by letter. The letter will identify the date on which the review period begins. The notice must include:

(i) *Manufacturer's name.* The name and address of the manufacturer of the new chemical substance and the name and telephone number of a technical contact must be provided.

(ii) *Type of exemption.* The exemption notice must indicate that the manufacturer is seeking a low volume exemption.

(iii) *Chemical identification*—(A) *Class 1 substances* (chemical substances whose composition can be represented by a definite structural

diagram). The chemical name (preferably Chemical Abstract Services (CAS) or International Union of Pure and Applied Chemistry (IUPAC) nomenclature), the molecular formula, CAS Registry Number (if available), and a structural diagram.

(B) *Class 2 substances* (chemical substances that cannot be fully represented by a structural diagram). The chemical name, the molecular formula, the CAS Registry Number (if available). The notice must identify the immediate precursors and reactants by name CAS Registry Number (if possible). The notice must include a partial or incomplete structural diagram (if available). Chemical names for such substances should be developed according to the guidelines in the TSCA Chemical Substance Inventory, Initial Inventory, Volume 1.

(C) *Polymers.* Monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry Number (if available); typical percent of each monomer and other reactants used in the polymer (by weight percent of total polymer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram (if possible). The notice must provide estimates of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight and describe how the estimates were obtained. This information must be provided to the extent it is known or reasonably ascertainable by the submitter.

(D) *Impurities.* Impurities anticipated to be present in the new chemical substance by name, CAS Registry Number (if known), and weight percent of the total substance. If there are unidentified impurities, the notice must include an estimate of their total weight percent. Information on impurities must be provided to the extent that it is known to or reasonably ascertainable by the submitter.

(E) *Generic name.* If the manufacturer claims the chemical identity of the new chemical substance confidential, he or she must submit a generic name in accordance with paragraph (k)(2) of this section. The name should be only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. In should reveal the specific chemical indentity to the maximum extent possible.

(iv) *Description of use.* Each use for which the chemical substance would be manufactured by function and application (e.g., spray adhesive in the manufacture of laminates). The description of use must indicate whether the use is industrial, commercial, or consumer.

(v) *Site of manufacture* (except for chemical substances that are imported). The notice must state the name and address of the site or sites of manufacture of the new chemical substance.

(vi) *Certification.* The manufacturer must certify that:

(A) The manufacturer intends to manufacture or import the new chemical substance for commercial purposes, other than in small quanitities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(vii) *Test data.* The manufacturer must submit all test data in its possession or control which are related to the effects of the new chemical substance on health or the environment.

(viii) *Exposure controls.* The manufacturer may also provide information on exposure controls or other controls for the new chemical substance. Where a manufacturer provides such information to support the exemption notice, the manufacturer must maintain those controls throughout the period of the exemption.

(ix) *Sanitized copy of notice.* (A) The manufacturer must make all claims of confidentiality in accordance with paragraph (k) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (k)(3) of this section.

(B) If the submitter does not provide the second copy, the submission is incomplete.

(2) *Incomplete notices.* If EPA receives a submission which does not include all of the information required under paragraph (e) of this section, the submission will be determined to be incomplete by the Director of the Office of Toxic Substances. The exemption review period will not begin until EPA receives all required information.

(f) *Review period.* EPA will review the notice submitted under paragraph (e) of this section to determine whether the new chemical substance is eligible for the exemption. The review period will end 21 days after receipt of the notice by EPA. Upon expiration of the 21-day review period, if EPA has taken no action, the manufacturer may begin to manufacture the new chemical substance under the other terms of this exemption.

(g) *Notice of ineligibility*—(1) *During the review period.* If the Assistant Administrator for Pesticides and Toxic Substances determines during the review period that the new chemical substance does not meet the terms of this section, or that there are issues concerning toxicity or exposure that require further review, the Assistant Administrator will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the issues and explains why they are unresolved. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act.

(2) *After the review period.* (i)(A) If at any time after the end of the review period specified in paragraph (f) of this section, the Assistant Administrator for Pesticides and Toxic Substances makes a preliminary determination that the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of this section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the new chemical substance after receiving notice under paragraph (g)(2) (i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (g)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of notification may not begin manufacture until EPA makes its final determination under paragraph (g)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (g)(2)(i) of this section may submit detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section within 15 days of receipt of written notification.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (g)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of

the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Assistant Administrator determines that the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 24 hours of the telephone notification under paragraph (g)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, or use until it submits a notice under section 5(a)(1) of the Act and Part 720 of this chapter and the notice review period has ended.

(vi) If the Assistant Administrator determines that the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (g)(2)(i) of this section, and

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and Part 720 of this chapter within 15 days of receipt of the telephone notification under paragraph (g)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, and 17 of the Act.

(h) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify for the exemption, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information.

(i) *Changes in site or use.* (1) Chemical substances manufactured under this section must be manufactured at the site or sites described and for the uses described in the exemption notice submitted in accordance with paragraph (e) of this section.

(2)(i) Any person who manufactures a new chemical substance described in paragraph (c) of this section must comply with the provisions of this section before manufacturing the new chemical substance at a site that was not reported in a previous exemption notice, including submission of a new notice under paragraph (e) of this section.

(ii) Any person who manufactures a new chemical substance described in paragraph (c) of this section must comply with the provisions of this section before manufacturing the new chemical substance for a use that was not reported in a previous exemption notice, including submission of a new notice under paragraph (e) of this section.

(3) In an exemption notice informing EPA of a change in site or use, the manufacturer is not required to provide information submitted to EPA in a previous exemption notice on that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and the new site or use. The notice must also include a certification by the manufacturer, as described in paragraph (e)(1)(vi) of this section.

(j) *Customer notification.* (1) Manufacturers of a new chemical substance described in paragraph (c) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice. The manufacturer must also inform processors and industrial users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) If the manufacturer learns that a customer is processing or using the exempt substance in violation of use restrictions or without imposing prescribed controls, the manufacturer must cease distribution of the substance to the customer immediately. The manufacturer must also report this action to EPA within 15 days under paragraph (h) of this section.

(k) *Confidentiality.* (1) If the manufacturer submits to EPA under this section information which it claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in Part 2 of this Title. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide a generic chemical name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the submitter will be subject to EPA review and approval in accordance with the procedures specified in § 720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(l) *Determination of first manufacturer of a new chemical substance.* (1) A person who intends to manufacture a new chemical substance under this section may determine whether that particular substance is already being manufactured under that section and, therefore, whether the person is eligible for the exemption, by submitting a notice on the substance under paragraph (e) of this section. EPA will inform the manufacturer within the 21-day review period if the manufacturer is not eligible for the exemption because another person is already manufacturing the substance under the exemption.

(2) Alternatively, the manufacturer may ask EPA whether another manufacturer is already producing the new chemical substance under this section. EPA will respond to this inquiry only if EPA determines that the manufacturer making the inquiry has shown a *bona fide* intent to manufacture the substance under the terms of this section.

(i) To establish a *bona fide* intent to manufacture a substance under this section, the manufacturer must submit to EPA:

(A) The specific chemical identity of the substance that the person intends to manufacture.

(B) A signed statement that the person intends to manufacture that chemical substance under the terms of this section.

(C) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture the chemical substance.

(D) An elemental analysis.

(E) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(ii) If an importer cannot provide all the information required by paragraph (1)(2)(i) of this section because it is claimed confidential business information by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the information directly to EPA.

(iii) The Director of the Office of Toxic Substances will promptly examine the manufacturer's submission.

(A) If the Director determines that the manufacturer has not shown a *bona fide* intent to manufacture the new substance under the terms of this section, the Director will promptly notify the manufacturer. The manufacturer may then submit a notice under paragraph (e) of this section or a notice under section 5(a)(1) of the Act.

(B) If the Director determines that the manufacturer has shown a *bona fide* intent to manufacture the new chemical substance under the terms of this section, the Director will promptly inform the manufacturer whether the substance is being manufactured under this section. If the substance is not being manufactured under this section, the manufacturer may submit a notice under paragraph (e) of this section. If the new chemical substance is being manufactured under this section, the manufacturer must submit a notice under section 5(a)(1) of the Act.

(m) *Volume limitation.* A person manufacturing a new chemical substance under this section may not manufacture more than 1,000 kg of the substance during each 12-month period following the date the review period described in paragraph (f) of this section expires.

(n) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: Document Control Officer (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. E-201, 401 M St., SW., Washington, D.C. 20460.

(o) *Recordkeeping.* (1) Each manufacturer of a new chemical substance described in paragraph (c) of this section must maintain records of (i) the annual production volume of the new chemical substance under the exemption, and (ii) documentation of information in the exemption notice and compliance with the terms of this section. Records maintained under this paragraph must be retained for 5 years after date of their preparation.

(2) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA permit such person at all reasonable times to have access to and to copy records kept under paragraph (o)(1) of this section.

(3) The manufacturer must submit the records listed in paragraph (o)(1) of this section to EPA upon written request by the Director of the Office of Toxic Substances. Manufacturers must provide these records within 15 working days of receipt of this request.

(p) *Compliance.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616)].

(Approved by the Office of Management and Budget under control number 2070-0012)

(Sec. 5, Pub. L. 94-496, 90 Stat. 2012 (15 U.S.C. 2604))

[FR Doc. 85-10145 Filed 4-25-85; 8:45am]

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA 6655]

Suspension of Community Eligibility Under the National Flood Insurance Program; New York et al.

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: This rule lists communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the flood plain management requirements of the program. If FEMA receives documentation that the community has adopted the required flood plain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the Federal Register.

EFFECTIVE DATES: The third date ("Susp.") listed in the fourth column.

FOR FURTHER INFORMATION CONTACT: Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, (202) 646-2717, 500 C Street, Southwest, FEMA—Room 509, Washington, D.C. 20472.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001-4128) unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance with program regulations (44 CFR Part 59 et. seq.). Accordingly, the communities are suspended on the effective date in the fourth column, so that as of that date flood insurance is no longer available in the community. However, those communities which, prior to the suspension date, adopt and